

# **EXHIBIT A**

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); Schering-Plough Corporation ("Schering"), a New Jersey corporation with its principal place of business in Kenilworth, New Jersey; and Charles Alcorn, Beatrice Manning and G. Raymond Pironti, Jr. (the "Relators"), through their authorized representatives. Collectively, all of the above shall be referred to as "the Parties."

II. PREAMBLE

A. WHEREAS, this Agreement addresses the United States' civil claims against Schering for the conduct described in the Information to be filed in United States v. Schering Sales Corporation, Criminal Action No. [to be assigned] (Eastern District of Pennsylvania) (the "Criminal Action"), for the conduct alleged in Preamble Paragraph H below, and for the conduct described in the currently pending allegations in United States ex rel. Charles Alcorn, Beatrice Manning and G. Raymond Pironti, Jr. v. Schering-Plough Corporation, Civil Action No. 98-5688 (Eastern District of Pennsylvania) (the "Civil Action");

B. WHEREAS, Schering Sales Corporation will enter into a plea agreement with the United States pursuant to which, if that

agreement is approved by the Court, Schering Sales Corporation will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one count Information alleging a violation of Title 42 U.S.C. § 1320a-7b, arising from the company's payment of a data fee in connection with an effort to maintain formulary status for Claritin at an HMO customer, as more fully described below, and will pay a criminal fine in the amount of Fifty-Two Million, Five Hundred Thousand dollars (\$52,500,000) pursuant to the plea of guilty. OIG-HHS represents that the guilty plea of Schering Sales Corporation in this parallel Criminal Action and the resulting mandatory exclusion of Schering Sales Corporation does not give rise to a mandatory exclusion action against Schering under 42 U.S.C. § 1320a-7(a);

C. WHEREAS, on or about October 27, 1998, Relators filed the Civil Action in the United States District Court for the Eastern District of Pennsylvania, assigned Civil Action No. 98-5688. The United States intervened in the Civil Action against Schering, and filed a Complaint-in-Intervention on July 30, 2004;

D. WHEREAS, at all relevant times, Schering marketed a broad range of drugs with Schering's largest selling prescription products being the Claritin family of non-sedating antihistamines;

E. WHEREAS, at all relevant times Schering employed a range of strategies to gain access to managed care customers' formularies including providing discounts or rebates on all of the Schering products maintained on their formularies;

F. WHEREAS, at all relevant times, the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, required participating manufacturers to provide discounted pricing to Medicaid pursuant to specific rules based upon the lowest price at which the manufacturer sold its products to certain commercial customers. The purpose of these specific rules is to ensure that Medicaid receives favorable pricing in relation to the pricing available in the commercial marketplace. Schering entered into a rebate agreement with the Health Care Financing Administration ("HCFA"), currently known as the Centers for Medicare & Medicaid Services ("CMS"), and Schering's drug products were at all relevant times covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§1396a(a)(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with CMS, Schering generally agreed: (i) to report quarterly to CMS its average manufacturer price and best price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1);

G. WHEREAS, at all relevant times, Schering participated

in the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92. As a participant in the Drug Pricing Program, Schering entered into an agreement with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, hemophilia treatment centers, and disproportionate share hospitals, as defined in 42 U.S.C. § 256b(a)(4) (the "PHS entities"). Under the Drug Pricing Program and its agreement with HHS, Schering generally agreed that the amount that Schering required the PHS entities to pay for drug products would not exceed the average manufacturer price, as reported by Schering to CMS in the previous calendar quarter, minus a specified rebate percentage that was derived in part, from the Medicaid rebate paid by Schering in the preceding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a);

H. WHEREAS, the United States contends that it has certain civil claims against Schering under the False Claims Act, 31 U.S.C. §§ 3729-33, the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal statutes, and/or common law doctrines as specified in Paragraph 4 below for failing to include in best price certain price concessions on Claritin that Schering provided to two of its largest managed care customers, Cigna and PacifiCare. In each instance Schering agreed to provide these managed care customers with unique items and services of value, including cash

incentives, deeply discounted products and health management programs that were, in the specific context of those customer relationships, clearly targeted and calculated to reduce the health plan's effective cost for Claritin. Schering contends that these additional value offerings were generally permissible and had no impact on best price. The United States contends that, in the particular circumstances of the transactions described below, Schering's failure to treat these value items as additional discounts in the calculation of its Claritin best price unlawfully denied the same price reductions to Medicaid and the PHS entities. The specific Covered Conduct is as follows:

(i) The CIGNA Transaction

During the course of 1996 and 1997, Schering and CIGNA entered into agreements that were to govern the pricing that would be available to CIGNA on all of the Schering drugs that CIGNA made available to its enrollees through its health plan formularies, including the Claritin family of products. The agreements each had terms of three years.

Maintaining this relationship with CIGNA was important to Schering. Each year, CIGNA's enrollees utilized well over \$100 million of the Schering drugs included on CIGNA health plan formularies, with Claritin comprising a larger portion of that utilization than any other single drug. Under the 1997 agreements, in exchange for the utilization of its drugs, Schering provided CIGNA with a broad range of discounts and

rebates of more than \$20 million per year. In addition, Schering also provided CIGNA with valuable health management programs that CIGNA in turn provided to its members.

In 1998, less than one year into the 1997 agreements' three-year term, CIGNA began voicing concerns that Schering's direct-to-consumer advertising had resulted in higher utilization of Claritin than it had projected and therefore also higher costs. CIGNA also complained that the per-unit price it was paying for Claritin was substantially higher than the per-unit price it was paying for Allegra, its primary competitor. CIGNA asked Schering to increase the Claritin discounts and rebates it was providing to CIGNA under the agreements to meet Allegra's price.

Schering refused CIGNA's request for additional discounts and rebates on Claritin. In response, CIGNA threatened to breach the 1997 agreements and stop reimbursing for certain products in the Claritin family of non-sedating antihistamine products (including the main Claritin tablet product, two Claritin/decongestant tablet products, and a rapidly dissolving form of Claritin tablet called a "Reditab").

In September 1998, based upon Schering's refusal to provide additional Claritin price concessions, CIGNA's Pharmacy and Therapeutics ("P&T") Committee took the drastic and unusual step of voting to recommend to CIGNA's senior management that the Claritin products be removed from CIGNA's health plan formularies. Upon learning of the vote, Schering discussed with

CIGNA what it would take financially for CIGNA's senior management to reject the P&T Committee's recommendation. CIGNA told Schering that it would need to "bring its Claritin price down to Allegra" in order to avoid having it removed from formulary.

While Schering was willing to address CIGNA's Claritin pricing concerns, Schering was aware that providing CIGNA with the specific additional Claritin discounts and rebates it was requesting would have required Schering to report lower Claritin best prices to the government, which would have resulted in increased rebates going to Medicaid.

Instead, Schering ultimately provided CIGNA with a package of other types of payments and services - including a large cash payment for a data report with no practical value to Schering - that was specifically tailored to deliver an amount of value that Schering believed would address CIGNA's Claritin cost concerns. Notwithstanding that the specifically tailored package of benefits Schering provided to CIGNA effectively decreased CIGNA's Claritin prices as CIGNA had requested, the best prices Schering reported to the government did not reflect any of these value offerings. In the specific context of the CIGNA transaction, Schering's failure to factor these offerings into its best prices thereby deprived the Medicaid program of additional rebates it should have received.

The fact that Schering's multi-million dollar package



was intended as a Claritin price concession was evidenced by both the context and content of the deal. In the presentation that Schering made to CIGNA when proposing the deal, Schering provided CIGNA with a calculation explicitly showing how the package of benefits effectively closed the gap between CIGNA's costs for Claritin and Allegra. That the intent of the deal was to reduce the price of Claritin is further evidenced by the combined components of the deal.

First, and most critically demonstrating the improper nature of the deal, Schering agreed to make annual cash payments to CIGNA of approximately \$2.5 million that were described as "data processing fees." These payments, the linchpin of the value package, were in exchange for CIGNA's agreement to provide Schering with annual reports containing detailed CIGNA regional utilization data that Schering could use for marketing purposes. In reality, however, under the 1997 agreements, CIGNA was already required to provide (and had been providing) Schering with the same detailed regional data for purposes of calculating Schering's rebate payments to CIGNA, and when Schering purchased the first of the annual reports from CIGNA in 2000, it was never used. The annual reports were therefore of no practical value to Schering except insofar as they amounted to additional Claritin discounts that Schering improperly excluded from its best price calculations.

Second, Schering agreed to provide CIGNA's staff model HMO with \$3 million in deep discounts on its purchases of

Claritin Reditabs, which contained the same active ingredient as the flagship Claritin tablet product but in a rapidly dissolving form. Schering withheld these discounts from its calculation of the best prices it reported to the government for purposes of Medicaid pricing on the basis of on an exception for deeply discounted or "nominal" priced drugs. In practice, however, Schering understood that CIGNA would direct physicians in its staff model HMO to substitute some of the prescriptions of its regularly priced Claritin tablets, where clinically appropriate, with prescriptions of the deeply discounted and therapeutically identical Claritin Reditabs. Therefore, in effect, under these circumstances, the deep discounts on Claritin Reditabs were hidden price concessions on Claritin tablets.

Third, Schering agreed to provide CIGNA with the equivalent of an interest-free loan through pre-paying rebates owed under its 1997 agreements. Originally under those agreements, Schering made quarterly rebate payments to CIGNA after the end of the quarter to which the rebate pertained. Under a new arrangement, however, Schering agreed to accelerate those payments by making an estimated rebate payment before the end of the quarter to which the rebate pertained, thus giving CIGNA the time benefit of receiving its payments before the end of the quarter. The time value of those pre-payments, which effectively increased the value of the rebates Schering paid CIGNA, was intended to complete the package of benefits Schering provided to CIGNA to maintain Claritin on formulary, but was not

factored into the best prices that Schering reported to the government. Under these circumstances, the pre-paid rebates were thus also hidden discounts on Claritin.

Finally, under a separate health management contract, Schering also agreed to expand the range of health management services it was providing to CIGNA and to extend its health management programs to additional CIGNA regional sites. For those services, Schering agreed to charge CIGNA a fixed fee of \$.29 per member per year. That fee, however, was too low to cover Schering's expenses for the expanded programs and Schering was therefore, in effect, subsidizing a portion of the health management costs that CIGNA would otherwise have incurred. In addition, Schering also agreed to hire and pay a CIGNA subsidiary to handle certain administrative functions related to the health management programs. In the specific context of the CIGNA transaction, it was apparent that the value of this health management arrangement was designed to complement the hidden Claritin discounts that Schering was providing to CIGNA in order to bridge the price gap between Claritin and Allegra.

(ii) The PacifiCare Transaction

Like CIGNA, PacifiCare has historically been one of Schering's most important managed care customers, accounting for more than \$75 million of utilization of Schering's drugs each year. Also, as with CIGNA, after the advent of Schering's direct-to-consumer marketing in 1997, PacifiCare began complaining about the price it was paying for Claritin. It

threatened to remove Claritin from its formularies in favor of the less expensive Allegra in order to decrease its drug costs if Schering was unwilling to provide additional price concessions. In response, Schering entered into an agreement with PacifiCare (through a subsidiary) in 1998 (the "1998 Amendment").

The 1998 Amendment specifically addressed PacifiCare's Claritin cost concerns. It included provisions for pre-paid rebates as well as deep discounting or "nominal" pricing on certain Schering products, calculated to reduce PacifiCare's effective cost for Claritin. The most significant value offering in the 1998 Amendment, however, was a novel "risk share" arrangement under which Schering agreed to cover a portion of PacifiCare's annual antihistamine costs. That arrangement was triggered in any year in which PacifiCare's total antihistamine costs - whether for Schering or competitor products - increased by more than 10%. Schering then became responsible for PacifiCare's total antihistamine cost increase up to a cap of 25% of the prior year's costs. For 1998, 1999, and 2000, Schering paid PacifiCare a total of approximately \$25 million pursuant to this "risk share" provision.

Schering also entered into two additional contracts with PacifiCare during the course of 1998 to implement pilot health management programs at PacifiCare sites. Under the first agreement, Schering agreed to implement a "Seniors Health and Wellness" demonstration project designed to evaluate educational and member retention efforts targeted at PacifiCare's senior

citizen population. Under the second agreement, Schering agreed to help PacifiCare develop internet-based health management tools.

From the specific context of the negotiation and implementation of these arrangements, it was apparent that Schering tailored and intended their value to address PacifiCare's concern that Claritin was more expensive than its competitor Allegra. Schering's failure under the specific circumstances of the Cigna and PacifiCare transactions to include the value of these arrangements in its reported best prices improperly denied the government the benefit of commercial price concessions provided to these managed care customers. Had Schering instead provided Cigna and PacifiCare with the actual Claritin additional discounts and rebates to address their stated Claritin pricing concerns, Schering would have needed to increase the discounts it was providing on Claritin to bring its Claritin price down to the price of Allegra.

The United States contends that from the First Quarter of 1998 through the Fourth Quarter of 2002, Schering knowingly misreported its best prices to CMS for the Claritin tablet family of drugs by failing to include the value of the above arrangements as additional discounts on such drugs resulting in the unlawful denial of these price reductions to the Medicaid Program. The United States further contends that from the First Quarter of 1998 through the Fourth Quarter of 2002, Schering

overcharged the PHS entities for the Claritin tablet family of drugs by failing to include the value of the above arrangements in the calculation of pricing to which the PHS entities were entitled. The specific Claritin National Drug Code numbers affected are 00085-0458 (Claritin Tablets), 00085-0635 (Claritin D-12), 00085-0640 (Claritin D-24), 00085-1233 (Claritin D-24), 00085-1128 (Claritin Reditabs).

Schering's conduct as described in the Criminal Information, the currently pending claims in the Civil Action and the specific covered conduct in Preamble Paragraph H are hereafter referred to as the "Covered Conduct";

I. WHEREAS, the United States also contends that it has certain administrative claims against Schering under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the Civil Monetary Penalties Laws, 42 U.S.C. § 1320a-7a, for the Covered Conduct;

J. WHEREAS, other than such admissions as Schering Sales Corporation makes in connection with its anticipated entry of a plea of guilty pursuant to its plea agreement with the United States, Schering denies the remaining allegations of the United States as set forth herein and in the Civil Action and denies that it has any liability or engaged in any wrongful conduct in connection with the Covered Conduct or the conduct alleged in the Civil Action;

K. WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below, which settlement has the effect of equating the price of Claritin to that of Allegra from the first quarter of 1998 to the fourth quarter of 2002.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Schering agrees to pay to the United States and the Participating States, collectively, the sum of Two Hundred Eighty-Two Million, Three Hundred Forty-Three Thousand, and Twelve dollars (\$282,343,012). This sum shall constitute a debt immediately due and owing to the United States and the Participating States on the Effective Date of this Agreement. This sum shall be paid in two equal installments. The first installment shall be paid no later than seven business days after Schering receives written payment instructions from the United States and after all of the following shall have occurred: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, (2) the stipulated dismissal described in Paragraph 10 of this Agreement is filed and copies provided to Schering's attorneys, and (3) the Court accepts the Fed. R. Crim.

P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence. The second installment shall be paid no later than March 4, 2005 pursuant to written payment instructions from the United States. The foregoing payments are to be made to the United States and the Participating States, under the following conditions:

A. Schering and the United States agree that the sum of One Hundred Sixty-Five Million, Two Hundred Seventy-Four Thousand, Four Hundred Ninety-Two dollars (\$165,274,492) shall represent the Federal Share (the "Federal Settlement Amount"). It is further recognized that the Federal Settlement Amount will be reduced by Thirty-One Million, Three Hundred Three Thousand, One Hundred Sixty dollars (\$31,303,160), the amount already refunded to the United States from the States as a result of the Schering payments to the States for the Claritin family of drugs best price refiling in 2003 pursuant to the PacifiCare relationship. Schering agrees to pay interest at the rate of 4.00 percent on the Federal Settlement Amount from the Effective Date of this agreement and continuing until and including the day before complete payment is made.

B. Schering and the Participating State Medicaid programs agree that the sum of One Hundred Seventeen Million, Sixty-Eight Thousand, Five Hundred Twenty dollars (\$117,068,520) shall represent the States' share (the "State Settlement Amount") under terms and conditions agreed upon by Schering and the



Participating States (the "State Settlement Agreement"). The State Settlement Amount shall be paid to an escrow account pursuant to the State Settlement Agreement no later than seven business days following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, (2) the stipulated dismissal described in Paragraph 10 of this Agreement is filed and copies provided to Schering's attorneys, (3) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence, or (4) the model State Settlement Agreement is agreed to by or on behalf of the Participating States and Schering. It is further recognized that the States' Settlement Amount will be reduced by Twenty-Two Million, Two Hundred Seventy-Six Thousand, Seven Hundred Sixty-Four dollars (\$22,276,764), the amount already received by the Participating States from Schering as a result of the Claritin family of drugs best price refiling in 2003 pursuant to the PacifiCare relationship.

2. Schering shall pay to the PHS entities the sum of no less than Ten Million, Six Hundred Twenty-Six Thousand, Four Hundred Seventy dollars (\$10,626,470) (the "PHS Settlement Amount"). Schering agrees to present for review and audit the underlying calculations used to determine the correct price(s) for the PHS entities during the relevant time periods. Schering agrees that if it is determined that Schering owes any additional amounts to

any PHS entity, based upon the allegations regarding the Cigna and PacifiCare transactions described above, Schering agrees to pay any additional amount required to make that entity whole. The PHS Settlement Amount shall be paid by Schering to each affected PHS entity by check within thirty (30) days after all of the following shall have occurred: (1) this Agreement is fully executed by the Parties and delivered to Schering's attorneys, (2) the stipulated dismissal described in Paragraph 10 of this Agreement is filed and copies provided to Schering's attorneys, and (3) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence.

3. If Schering Sales Corporation's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Schering. If either the United States or Schering exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten business days of the Court's decision, the parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Schering accepts service of the United States' Complaint-in-Intervention effective as of the date of recision, waives any claim of defect regarding service of

process, and waives any affirmative defense based in whole or in part on the running of the statute of limitations during the period from March 4, 2004 through the date of rescission.

4. Subject to the exceptions in Paragraph 5 below, and in consideration of the obligations of Schering set forth in this Agreement, conditioned upon Schering's payment in full of the Federal, State, and PHS Settlement Amounts, subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), and subject to the acceptance by the United States District Court for the Eastern District of Pennsylvania of Schering Sales Corporation's guilty plea described in Preamble Paragraph B, the United States, on behalf of itself, and its officers, agents, agencies, and departments, agrees fully and finally to release waive and discharge Schering, its past and present parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to the federally-funded programs in this Agreement for which the United States has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O,

Subpart I, 0.45(d) (1995); and common law claims including claims for fraud, unjust enrichment, payment by mistake, breach of contract, or disgorgement, for the Covered Conduct.

5. Notwithstanding any term of this Agreement, the United States specifically does not in this Agreement release Schering, its past and present parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, and its present and former directors, officers, agents, and employees from any and all of the following: (a) any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Schering; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Schering, its past and present parents, affiliates, divisions, and subsidiaries and their predecessors, successors and assigns.

6. In consideration of the obligations of Schering set forth in this Agreement and the Corporate Integrity Agreement ("CIA") referred to in ¶ 24 below and incorporated herein by reference), conditioned on Schering's payment in full of the Federal, State, and PHS Settlement Amounts, and subject to Paragraph 18 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), OIG-HHS agrees to release and refrain from instituting, directing, recommending or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Schering, its past and present parents, affiliates, divisions, and subsidiaries, and their predecessors, successors, and assigns under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct, except as reserved in Paragraph 5 above, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any mandatory statutory obligations to exclude Schering from the Medicare, Medicaid, or other Federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5 above.

7. The Relators agree that the settlement of the Civil Action is fair, adequate, and reasonable under all the circumstances, and agree not to challenge this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. 3730(c)(2)(B).

8. Upon the United States' receipt of Schering's payment of the Federal Settlement Amount, the Relators, for themselves, their heirs, successors, agents, trustees, beneficiaries and assigns, fully and finally release, waive and forever discharge Schering, its past and present parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, and their present and former directors, officers, agents and employees from any claim, demand, expenses, debts, liabilities, obligations, costs, damages, injuries, actions and causes of action, that the Relators have or may have that arise under or relate to any of the allegations in the Civil Action and/or the Covered Conduct, except as they relate to a statutory claim for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d). The Relators hereby represent and warrant that no other individual or entity is entitled to assert any matter released in this paragraph in or through the Relators' right.

9. The United States agrees to pay the Relators Thirty-One Million, Six Hundred Sixty-Two Thousand, One Hundred Seventy-

Three Dollars (\$31,662,173.00) as relators' share of the proceeds pursuant to 31 U.S.C. § 3730(d). The United States will pay the Relators' share on a pro rata basis within 21 days of receipt of the Federal Settlement Amount from Schering. Upon receipt of Relators' share, Relators' for themselves and their successors, agents, attorneys and assigns, fully and finally release, waive, and forever discharge the United States and the Participating States from any claims pursuant to 31 U.S.C. § 3730, including 31 U.S.C. §§ 3730(b), (c), (d), and (d)(1), and any state False Claims Acts, respectively, for a share of the proceeds of the Civil Action, from any claims arising from the filing of the Civil Action (including without limitation any claim to a share of any recovery that may be obtained by the United States and Participating States against any other defendant named by the Relators in their Complaint) and in full settlement of their claims under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

10. A stipulation of dismissal will be filed upon execution of this agreement stating that, upon payment in full of the settlement amounts, the Court will dismiss the case with prejudice. When payment in full of the second installment payment is received by the United States, the Parties shall jointly notify the Court that the United States' claims and the remaining

claims by the Relators in the Civil Action shall be dismissed with prejudice pursuant to this stipulation and consistent with the terms of this Agreement, with the sole exception of those statutory claims reserved by the Relators for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d), which shall not be dismissed, unless those claims are settled and the Court is so informed by Schering and the Relators.

11. Schering waives and shall not assert any defense it may have to criminal prosecution or administrative action relating to the Covered Conduct, which defense may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Schering agrees that this Agreement is not punitive in purpose or effect.

12. Schering, on behalf of itself and its past and present parents, divisions, and subsidiaries, and affiliates, their predecessors, successors and assigns, fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Schering has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees,



servants, and agents, related to or arising from the United States' investigation and prosecution of the Civil Action, the Criminal Action, and the Covered Conduct up to the Effective Date of this Agreement.

13. In consideration of the obligations of the Relators set forth in this Agreement, Schering, on behalf of itself, its past and present parents, divisions, subsidiaries, and affiliates, their predecessors, successors and assigns, fully and finally releases, waives and discharges the Relators and their successors, assigns, and agents from any claims Schering has asserted, could have asserted, or may assert in the future against the Relators arising from the filing of the Civil Action and the United States' investigation and prosecution of the Civil Action, the Criminal Action and the Covered Conduct.

14. The Settlement Amount that Schering must pay pursuant to this Agreement shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, any TRICARE Program ("TRICARE"), Federal Employees Health Benefit Programs ("FEHBP"), Veteran's Affairs Program ("VA"), Medicaid program payer, or any State payer, related to the Covered Conduct; and, if applicable, Schering agrees not to resubmit to any Medicare carrier or intermediary, TRICARE, FEHBP, VA, Medicaid program or any state payer any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal any such denials of

claims.

15. Schering agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation ("FAR") 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Schering, its predecessors, parents, divisions, subsidiaries, or affiliates, and its present or former officers, directors, employees, and agents in connection with the following shall be "Unallowable Costs" on contracts with the United States and under the Medicare Program, Medicaid Program, TRICARE, and FEHBP: (1) the matters covered by this Agreement and the related plea agreement; (2) the United States' civil and criminal investigation relating to matters covered by this Agreement; (3) Schering's investigation, defense, and any corrective actions undertaken in response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys fees); (4) the negotiation and performance of this Agreement and the plea agreement; (5) the payment of the Settlement Amount and any payment that Schering may make to the Relators for costs and attorneys fees, and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to the OIG-HHS. However, nothing in

this paragraph affects the status of costs that are not allowable based upon any other authority applicable to Schering.

b. Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately estimated and accounted for by Schering and Schering shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Schering, its predecessors, parents, divisions, subsidiaries, or affiliates to the Medicare, Medicaid, TRICARE, VA, or FEHBP programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Schering further agrees that within 60 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Schering, its predecessors, parents, divisions, subsidiaries, or affiliates and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the

inclusion of the Unallowable Costs. Schering agrees that the United States shall be entitled to recoup from Schering any overpayment, plus applicable interest, as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Schering or its predecessors, parents, divisions, subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Schering or its predecessors, parents, divisions, subsidiaries or affiliates' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the Unallowable Costs described in this Paragraph.

16. Schering agrees that it shall not seek payment for any of the monies owed under this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors. Schering waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims for payment covered by this Agreement.

17. Schering expressly warrants that it has reviewed its financial condition, that it is currently solvent within the

meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and that it is not aware of any reasonably foreseeable circumstances under which it would not remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Schering within the meaning of 11 U.S.C. Section 547(c)(1), and (b) have concluded that these mutual promises covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which Schering was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a).

18. In the event Schering commences, or another party commences, within 91 days of the Effective Date of this Agreement, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of Schering's debts, or seeking to adjudicate Schering as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Schering or for all or any substantial part of Schering's assets, Schering agrees as

follows:

(a) Schering's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Schering shall not argue or otherwise take the position in any such case, proceeding or action that: (i) Schering's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Schering was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Schering.

(b) If Schering's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Schering for the claims that would otherwise be covered by the releases provided in Paragraph 4 and 6, above. If the United States chooses to do so, Schering agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Schering from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that Schering shall not argue

or otherwise contend that the United States claims, actions, or proceedings are subject to an automatic stay; (ii) Schering shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 90 calendar days of written notification to Schering that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on March 4, 2004; and (iii) the United States has a valid claim against Schering in the amount of Two Hundred Ninety-Two Million, Nine Hundred Sixty-Nine Thousand, Four Hundred Eighty-Two dollars (\$292,969,482), which the United States recognizes has been partially satisfied by Fifty-Three Million, Five Hundred Seventy-Nine Thousand, Nine Hundred Twenty Four dollars (\$53,579,924), the amount that Schering has already paid as a result of its Claritin family of drugs best price refiling in 2003 pursuant to the PacifiCare relationship, and the United States may pursue its claim, in the case, action, or proceeding referenced in the first clause of this paragraph or in such other claim, action or proceeding it chooses to commence.

(c) Schering acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

19. The Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release

any claims against any other person or entity.

20. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid hereunder for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

21. Nothing in this Agreement shall limit Schering's right and/or obligation to refile best prices for the Claritin family of products pursuant to the Medicaid Rebate Program.

22. Except as reserved in Paragraph 8, each party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

23. Schering represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

24. Schering has entered into a CIA with OIG-HHS, and that CIA is incorporated into this Agreement by reference. Schering will immediately upon execution of this Agreement begin to implement its obligations under the CIA.

25. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the Eastern District of Pennsylvania, including any dispute regarding Relators' attorneys' fees reserved in Paragraph 8, except that disputes rising under the CIA incorporated herein by reference



shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

26. The undersigned Schering signatory represents and warrants that he is authorized by the Board of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement through their respective agencies and departments. The undersigned signatories for the Relators represent and warrant that they are authorized and lawfully empowered to execute this Agreement on behalf of the Relators.

27. The "Effective Date" of this Agreement shall be on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

28. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

29. This Agreement, together with the CIA incorporated by reference, and the referenced plea agreement described in Preamble Paragraph B, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement shall not be amended except by written consent of the Parties, except that only Schering and OIG-HHS must agree in writing to modification of the CIA.

30. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same Agreement.

UNITED STATES OF AMERICA

Dated: July 28, 2004 BY: Patrick L. Meehan  
PATRICK L. MEEHAN  
United States Attorney

Dated: July 28, 2004 BY: Virginia A. Gibson  
VIRGINIA A. GIBSON  
Assistant United States Attorney  
Chief, Civil Division

Dated: July 28, 2004 BY: Margaret L. Hutchinson  
MARGARET L. HUTCHINSON  
Assistant United States Attorney

Dated: July 28, 2004 BY: Andy Mao  
ANDY MAO  
United States Department of  
Justice - Civil Fraud Division

Dated: \_\_\_\_\_ BY: \_\_\_\_\_  
LARRY J. GOLDBERG  
Assistant Inspector General for  
Legal Affairs  
Office of Inspector General  
United States Department of Health  
and Human Services

UNITED STATES OF AMERICA

Dated: \_\_\_\_\_ BY: \_\_\_\_\_  
PATRICK L. MEEHAN  
United States Attorney

Dated: \_\_\_\_\_ BY: \_\_\_\_\_  
VIRGINIA A. GIBSON  
Assistant United States Attorney  
Chief, Civil Division

Dated: \_\_\_\_\_ BY: \_\_\_\_\_  
MARGARET L. HUTCHINSON  
Assistant United States Attorney

Dated: \_\_\_\_\_ BY: \_\_\_\_\_  
ANDY MAO  
United States Department of  
Justice - Civil Fraud Division

Dated: 14 July 2004 BY: Larry J. Goldberg  
LARRY J. GOLDBERG  
Assistant Inspector General for  
Legal Affairs  
Office of Inspector General  
United States Department of Health  
and Human Services

RELATORS

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES ALCORN, Relator

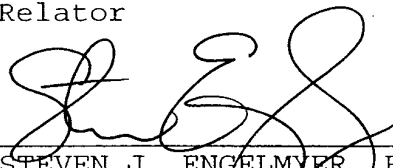
Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
BEATRICE MANNING, Relator

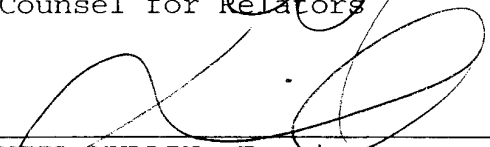
Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
G. RAYMOND PIRONTI, JR.,  
Relator

Dated: July 7, 2004

BY:   
STEVEN J. ENGELMYER, Esquire  
Counsel for Relators

Dated: June 26, 2004

BY:   
NEIL MULLIN, Esquire  
Counsel for Relators

RELATORS

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES ALCORN, Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
BEATRICE MANNING, Relator

Dated: June 29, 2004

BY: G. Raymond Pironti, Jr.  
G. RAYMOND PIRONTI, JR.,  
Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
STEVEN J. ENGELMYER, Esquire  
Counsel for Relators

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
NEIL MULLIN, Esquire  
Counsel for Relators

RELATORS

Dated: July 5, 2004

BY: Charles Alcorn  
CHARLES ALCORN, Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
BEATRICE MANNING, Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
G. RAYMOND PIRONTI, JR.,  
Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
STEVEN J. ENGELMYER, Esquire  
Counsel for Relators

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
NEIL MULLIN, Esquire  
Counsel for Relators

RELATORS

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
CHARLES ALCORN, Relator

Dated: 6/30/07

BY: Beatrice Manning  
BEATRICE MANNING, Relator

Dated: \_\_\_\_\_

BY: \_\_\_\_\_  
G. RAYMOND PIRONTI, JR.,  
Relator

Dated: \_\_\_\_\_


BY: \_\_\_\_\_  
STEVEN J. ENGELMYER, Esquire  
Counsel for Relators

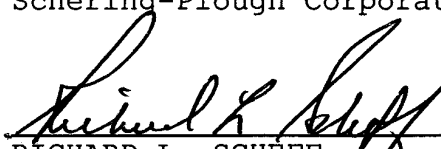
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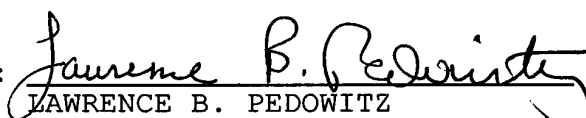
BY: \_\_\_\_\_  
NEIL MULLIN, Esquire  
Counsel for Relators



SCHERING-PLOUGH CORPORATION

Dated: July 29, 2004 BY:   
BRENT SAUNDERS  
Senior Vice President of  
Global Compliance and  
Business Practices  
Schering-Plough Corporation

Dated: July 29, 2004 BY:   
RICHARD L. SCHEFF  
Montgomery, McCracken, Walker  
& Rhoads, LLP

Dated: July 29, 2004 BY:   
LAWRENCE B. PEDOWITZ  
Wachtell, Lipton, Rosen & Katz